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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/622,146 | 01/02/2001 | Rolando Barbucci | 515-4204 | 8284 |

7590

03/20/2003

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EXAMINER

SERGEANT, RABON A

ART UNIT

PAPER NUMBER

1711

DATE MAILED: 03/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/622,146

Applicant(s)
Barbucci et al.

Examiner
Rabon Sergeant

Art Unit
1711



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 10, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☒ Claim(s) 25-35 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 10, 2003 has been entered.
2. Claims 25-35 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims not been further treated on the merits.
3. Claims 2, 5, and 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Firstly, within claims 2 and 21, it is inaccurate to state that the polyurethane comprises a repeating unit which is a diisocyanate. Since the isocyanate groups react to form the polymer, the repeating unit cannot be a diisocyanate; the repeating unit is the linkage that is formed by the reaction of the isocyanate groups

Secondly, within claims 5 and 24, applicants have referred to sulphated hyaluronic acid A_2 and B_2 ; however, A_2 and B_2 are not acids, they are derivatives. Within lines 5-9 of claim 24, the language essentially reads that the carboxylic function reacts with "alcohol of the alcohol". This language is confusing and fails to correspond to the language of similar claim 5.

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Lastly, within claim 20, the use of “obtainable” renders the claims indefinite, since it cannot be determined under what conditions the process is “able” to yield the product and under what conditions the process is unable to yield the product.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balazs et al. ('865) in view of WO 95/25751 and Halpern et al. ('114).

Balazs et al. disclose the covalent bonding of hyaluronic acid to polyurethane and the use of such materials in medical applications. See example 3.

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6. Balazs et al. are silent regarding the sulphate modification of the hyaluronic acid component; however, sulphated hyaluronic acids and their use with polyurethanes and within medical applications was known in the art at the time of invention. This position is supported by the teachings of WO 95/25751. See entire document and especially line 20 of page 28.

Furthermore, the covalent bonding of polysaccharides, including sulphate containing polysaccharides, to substrates, including isocyanate group containing substrates, to produce medical articles was known at the time of invention. See abstract; figures; and column 4, lines 20+ within Halpern et al.

7. In view of the teachings within Halpern et al. regarding the bonding of sulphate polysaccharides to isocyanate containing substrates, the position is taken that it would have been obvious to utilize the sulphated hyaluronic acids of WO 95/25751 as the hyaluronic acid component of Balazs et al., so as to arrive at the instant invention.

8. The examiner has considered applicants' arguments of February 10, 2003. However, applicants' response is considered to be deficient. Firstly, with respect to claims 1-19, applicants' arguments are not commensurate in scope with the limitations of the claims. Claims 1-19 neither exclude applicants' argued "surface" modification nor require a treatment in solution or "bulk". Secondly, with respect to claims 20-24, product by process claims are examined as product claims; the process carries weight only if it can be shown that the process causes formation of a patentably distinct product. In the instant case, applicants have failed to establish that the treatment in solution yields a patentably distinct product as compared to the treatment of the

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product of example 3 of the reference. It is noted that example 3 of the reference provides for the penetration of the polyurethane matrix by the hyaluronic acid component, prior to its crosslinking. One of ordinary skill would expect this penetrating characteristic of the disclosed process to cause covalent bonding of the components within the polymer matrix, rather than just at the surface. Therefore, applicants' representation of the process of example 3 and the argued resulting product appear to constitute oversimplifications of the disclosures within example 3. In the absence of more definitive comparisons or rationale, it is reasonable to expect that treatment in solution and treatment causing penetration of the polymer matrix yield comparable products, since each process seemingly yields a polymer modified throughout its mass. Lastly, applicants' response with respect to Examples 9-13 of the instant application is considered to be insufficient, because applicants refer to properties at the materials' surfaces, without providing a side by side comparison to the properties at the surface of the material of example 3. As a result, no comparisons have been provided relative to the closet prior art.

Any inquiry concerning this communication should be directed to R. Sergent at telephone number (703) 308-2982.


RABON SERGENT
PRIMARY EXAMINER

R. Sergent
March 19, 2003